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Prevention of Low Back Pain in the Military: A Randomized Clinical Trial

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14. ABSTRACT

The fourth year of the Prevention of Low Back Pain in the Military (POLM) clinical trial has been complete. The research team was able to complete all Year 4 tasks with the exception of completing primary data analyses. Study follow-up data collection was completed late in Year 4, thus requiring a no cost extension to allow for the statistical team to complete the analyses for manuscript preparation. In Year 4 the research team reported 1 platform presentation at a national physical therapy conference and 1 manuscript was accepted for publication in *Phys Ther*. Our preliminary analyses suggest that the core stabilization approach we are studying did not increase injury rates in other parts of the body, as has been suggested. Furthermore, those Soldiers performing the core stabilization did not experience as many days on medical profile from low back pain during the training period. These data provide important short term evidence to support our hypotheses related to long term prevention of low back pain.

15. SUBJECT TERMS
Primary prevention; cluster randomized trial; low back pain; core stabilization; biopsychosocial;

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INTRODUCTION

Low back pain (LBP) is a musculoskeletal condition that accounts for significant pain and disability, and consumes substantial medical and occupational costs annually. Specific to the United States Armed Forces, LBP was the second most common reason to seek healthcare and affects over 150,000 active duty Soldiers annually (MSMR 2003). Soldiers in the U.S. Army with LBP have the highest risk of disability 5 years after their injury. Furthermore, a military review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Therefore, reduction of disability from LBP is a significant research priority for the military.

Reduction of disability from LBP has been divided into 2 separate phases – primary and secondary prevention. Primary prevention refers to interventions and strategies that are implemented before a low back injury occurs.[2] Primary prevention reduces LBP related disability by reducing the total number of people who eventually experience an episode of LBP. Secondary prevention refers to interventions and strategies that are implemented during the acute episode of low back injury, before chronic symptoms occur.[1] Secondary prevention reduces LBP related disability by reducing the number of people who eventually experience chronic disability from LBP. We are proposing an innovative approach to LBP prevention by combining primary and secondary prevention strategies that have the potential to limit the development of chronic LBP in Soldiers.

Objective/Hypothesis

The purpose of the Prevention of Low Back Pain in the Military (POLM) trial is to determine if a combined prevention program is more effective at limiting the development of chronic LBP when compared to the effects of individual evidence-based prevention programs, or a traditional exercise program.

Specific Aims

Specific Aim 1: We will determine if a combined prevention program consisting of core stabilization exercise program (CSEP) and psychosocial educational program (PSEP) prevents the development of chronic LBP. During advanced individual training (AIT), United States Army Soldiers who volunteer will be randomly assigned to receive 1 of 4 prevention programs. Soldiers will be followed monthly during the first 2 years following AIT to measure LBP occurrence and severity with a web-based data collection system managed at the University of Florida.

Specific Aim 2: We will determine if the CSEP results in favorable changes in specific core musculature associated with reducing LBP. The CSEP activates specific core musculature that is important in preventing LBP. We will use real-time ultrasound imaging to measure changes in core musculature that occur during AIT. We will also determine if the PSEP results in a favorable change in LBP beliefs. The PSEP educates individuals in an evidence-based, psychosocial approach to the management of LBP, which can potentially decrease the likelihood of experiencing chronic LBP. We will use a validated self-report questionnaire to measure Soldiers' LBP beliefs regarding outcome and management. We will measure LBP beliefs at the beginning and end of AIT (a 12-week period).

Relevance: The results of this study will have several immediate applications for Soldiers. The widespread incorporation of effective preventative strategies will certainly result in a substantial reduction of LBP in the military. Programs that effectively prevent the occurrence and severity of LBP would benefit the U.S. Armed Forces by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers. For example, an average

cost of $136.02 per LBP visit was calculated for 2004. A 40% reduction in the recurrence of LBP after completing the CSEP would generate a cost savings of $3,343,230 by the 4th fiscal year (approximately 1/5 of the total cost of LBP for one FY).

Low back pain prevention programs are necessary to reduce the impact of musculoskeletal injury in the United States Military. Low back injuries are a significant cause of disability in the United States Army. For example in the United States Military, LBP was the second most common reason to seek healthcare and affected over 150,000 active duty Soldiers. Soldiers in the United States Army with LBP have the highest risk of disability 5 years after injury and a review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Clearly, quality clinical research producing evidence related to LBP prevention is warranted for the United States Military.

Programs that effectively prevent the occurrence and severity of LBP would benefit the United States Military by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers.

BODY

As outlined in our SOW, Year 3 was dedicated to dissemination of results. These tasks are outlined below:

Task 4: Dissemination of research findings

- Analyze and report pre-training findings
  - Scientific meeting (poster or platform presentation)
  - Manuscript submission
- Analyze and report post-training findings (Specific Aim #2 and #3)
  - Scientific meeting (poster or platform presentation)
  - Manuscript submission
- Analyze and report final findings (Specific Aim #1 and #3)
  - Scientific meeting (poster or platform presentation)
  - Manuscript submission

We met the first task of reporting the pre-training findings. However, we have not analyzed the results for the post-training (Aims #2 and #3) or the final findings (Aims #1 and #3). This study is a cluster randomized trial of over 4,000 US Army Soldiers in which we compared different exercise and education programs for the prevention of low back pain while performing active military service. The follow up period for this study is 2 years, and involves Soldiers stationed all over the world. Collecting the 2 year information ended up being quite difficult and resulted in a delay in collecting the primary outcome data at 2-years. This delay meant that the statistical analysis for the primary outcomes was also delayed. The delay was scientifically necessary because our primary aim of the study was looking at long term effects of the programs. However, 2-year data collection is now complete and the statistical analysis team has been briefed with plan to complete the analyses in Fall 2010. The no cost extension will allow the statistical team to complete all planned primary analyses for this study (Aims #1, #2, and #3) and also allow the statistical team to fully participate in the manuscripts reporting the primary results.

Dissemination of research findings for Year 4 occurred at the Combined Sections Meeting for the American Physical Therapy Association. POLM investigators reported original data at a platform presentations. Relevant content is reported below:

Title
The Effects of Traditional Sit-up Training Versus Core Stabilization Exercises on MSK Injury Rates in US Army Soldiers: A Cluster Randomized Trial (NCT00373009)

Funding:
Congressionally Directed Peer Reviewed Medical Research Program (#W81XWH-06-1-0564)

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Purpose/Hypothesis
Despite the longstanding incorporation of traditional bent-knee sit-ups in US Army physical training, sit-up training increases lumbar spine loading, potentially increasing the risk of experiencing musculoskeletal (MSK) injuries and low back pain (LBP). “Core stabilization” exercises have been recommended as an alternative based on evidence demonstrating improved abdominal and trunk muscle strength without excessive spine loading and the potential for decreasing the incidence of LBP and lower extremity (LE) injuries. in athletes. However, anecdotally some have postulated that the horizontal side support exercise, a common exercise included in core stabilization exercise programs, results in increased upper extremity injuries because of sustained increased pressure through the upper extremity during the exercise. Therefore, the purpose of this study was to explore the short-term effects of a core stabilization exercise program (CSEP) on MSK injury incidence and days of work restriction. We hypothesized that no differences would exist.

Number of Subjects
Subjects included Soldiers between 18-35 years of age participating in Advanced Individual Training (AIT) who had at least 1 injury that resulted in work restrictions (n=1141).

Materials/Methods
Soldiers were randomized to complete CSEP (n=542) or TEP (n=599). CSEP included exercises that target the transversus abdominus and multifidi musculature. TEP was comprised of exercises targeting the rectus abdominus, oblique abdominals, and hip flexor musculature. Research staff recorded all injuries (MSK and non MSK) that resulted in work restrictions, defined as limited duty days during training. Descriptive statistics were calculated to summarize the data. The independent variable was exercise group (CSEP vs. TEP). Dependent variables were MSK injury incidence (average number of injuries per Soldier and percentage of those with MSK injuries) as a whole and by body region: low back (LB), upper extremity (UE), and lower extremity (LE) and number of limited duty days. Differences in the percentage of those with MSK injuries were examined with chi-square; independent samples t-tests were used to examine differences in the average number of injuries per Soldiers and number of limited duty days. Alpha was set to 0.05 a priori.

Results
Mean age of subjects was 22.9±4.73 years. Out of 1141 Soldiers with at least 1 injury (MSK or non MSK), 511 (44.8%) experienced at least 1 MSK injury. No differences existed in the percentage of those with MSK injuries as a whole (TEP=42.9%; CSEP=46.9%, P=.179) or by body region: LB (TEP=11.0%; CSEP=13.3%, P=.241); UE (TEP=4.5%; CSEP=6.1%, P=.232); LE (TEP=30.7%; CSEP=31.5%, P=.762). There were also no differences in the number of MSK injuries per Soldier as a whole (TEP=1.22±.53; CSEP=1.26±.51, P=.41) or by body region: LB (TEP=.28±.49; CSEP=.33±.57, P=.25); UE (TEP=.11±.32; CSEP=.13±.38, P=.47) LE (TEP=.81±.61; CSEP=.78±.64, P=.59). Both groups experienced more lower extremity injuries than any other region (TEP = .81 ± .61; CSEP = .78 ± .64), however there was no difference between the groups (P=.59). Additionally, there was no difference in the number of limited duty days for MSK injuries as a whole (TEP=21.4±24.7; CSEP=20.36±16.9, P=.57) or specific to the UE (TEP=19.5±17.0; CSEP=24.0±23.1, P=.40) or LE (TEP=20.0±23.8; CSEP=19.5±15.6,

P=.81). Soldiers who experienced a LB injury did experience more limited duty days (TEP=8.26±14.5; CSEP=4.24±8.00, P=.049).

Conlcusions
MSK injury incidence was similar between the groups. CSEP and TEP during AIT. No increases in upper extremity injuries were observed in the CSEP group, failing to support the notion that the horizontal side support exercise results in increased upper extremity injuries, at least during a 12-week training period. CSCSEP did result in fewer limited duty days for LB injuries, perhaps indicating that a protective benefit for CSEP might be observed over a longer time period once the full dosing of the intervention has been realized. There was a higher risk of experiencing a lower extremity injury compared to other body regions for both groups, confirming previous data that lower extremity injuries are the most common injuries experienced during training.

Clinical Relevance
CSEP does not result in increased MSK injuries and may result in fewer limited duty days for those with a LB injury.

In addition to Tasks specific to Year 4, the following recurring Tasks occurred:

Task 5: Complete quarterly procedures (Years 1 – 4)
(**NOTE: Task 5 will be completed once per quarter**)
- Conference call between all investigators
- Prepare quarterly reports
    - Manual of Operations
    - Monitor human subjects and safety monitoring

Task 6: Complete annual procedures (Years 1 – 4)
(**NOTE: Task 5 will be completed once per year**)
- On-site meeting between principal investigators
- Prepare annual reports
    - Manual of Operations
    - Human subjects and safety monitoring
- Renew institutional human subjects approval

Task 7: Prepare future proposals (Year 4)
- Conference call to discuss future DOD proposals related to prevention/treatment of musculoskeletal pain
    - Utilize established study infrastructure for data collection and management
    - Maintain established investigative team
- Preparation of subsequent DOD proposal related to prevention/treatment of musculoskeletal pain
- Submission of subsequent DOD proposal related to prevention/treatment of musculoskeletal pain

These activities were completed in Year 4, with details outlined below:

- Communication Between Investigators
    - Use of shared on-line calendar
    - Conference calls scheduled, as needed
- Investigator Meeting
- Steven George, Deydre Teyhen, and John Childs met in San Diego, CA to discuss long term follow up plans and plans for final analysis dissemination.

- Institutional Review
    - BAMC human subject approval has been maintained continuously since February 2006, with appropriate modifications made as needed
    - University of Florida human subject approval has been maintained continuously since June 2006
    - USAMRMC HSRRB deferred review to BAMC June 2006
- Future proposal submitted
    - Proposal keeping research team intact was submitted for review to NIH. This proposal focused on prevention of lower extremity pain.
    - Proposal was unscored, plans for resubmission being considered.

KEY RESEARCH ACCOMPLISHMENTS

- No difference in short-term injury rates at any anatomical location for those performing the core stabilization exercise program (CSEP) as compared to the traditional exercise program (TEP) utilized in this study.

- In fact, fewer days on medical profile while in advanced individual training (AIT) from low back pain were reported for those Soldiers completing the CSEP.

REPORTABLE OUTCOMES

Published abstracts

- Childs JD, Teyhen DS, Wright AC, Dugan JL, Casey P, McCoy-Singh K, Weston A, **George SZ**. The effects of traditional sit-up training versus core stabilization exercises on musculoskeletal injury rates in US Army Soldiers: a cluster randomized trial (NCT00373009). *J Orthop Sports Phys Ther,* abstracted 2010.

Papers in press

- Childs JD, Teyhen DS, Casey PR, McCoy-Singh KA, Feldtmann AW, Wright AC, Dugan JL, Wu SS, **George SZ**. Effects of traditional sit-up training versus core stabilization exercises on short-term musculoskeletal injury rates in US Army Soldiers: A randomized clinical trial. *Phys Ther*, in press.

CONCLUSION

Overall

The research team was able to complete all Year 4 tasks in a timely fashion, with the exception of the final analyses. As previously discussed, these will be completed during the no-cost extension period as it is a matter of the data analyses being completed – all 2 year data collection has been completed. The final analyses will include the original outcomes in the proposed study, as well as data from the telephone follow-ups and health care utilization data added in Year 3.

So far, data from the trial provide encouraging preliminary results from the implemented exercise and education programs. These data have been disseminated through abstracts and manuscripts. It does not appear that performance of the core stabilization exercise program adversely affects injury rates, and may be associated with fewer days of low back pain.

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2. Frank JW, Kerr MS, Brooker AS et al. Disability resulting from occupational low back pain. Part I: What do we know about primary prevention? A review of the scientific evidence on prevention before disability begins. *Spine* 1996;21:2908-17.

APPENDICES

1. Galley proof of *Phys Ther* article (uncorrected)

Effects of Traditional Sit-up Training Versus Core Stabilization Exercises on Short-Term Musculoskeletal Injuries in US Army Soldiers: A Cluster Randomized Trial

John D. Childs, Deydre S. Teyhen, Patrick R. Casey, Kimberly A. McCoy-Singh, Angela W. Feldtmann, Alison C. Wright, Jessica L. Dugan, Samuel S. Wu, Steven Z. George

AQ: 2 **Background.**

Objective. The objective of this study was to explore the short-term effects of a core stabilization exercise program (CSEP) without sit-up training and a traditional exercise program (TEP) on musculoskeletal injury incidence and work restriction.

Design. The study was designed as a cluster randomized trial.

Setting. The setting was a 16-week training program at Fort Sam Houston (San Antonio, Texas).

Participants. The study participants were soldiers with a mean age of 22.9 years (SD=4,7, range=18–35) for whom complete injury data were available for analysis (n=1,141).

Intervention. Twenty companies of soldiers were cluster randomized to complete the CSEP (10 companies of 542 soldiers) or the TEP (10 companies of 599 soldiers). The CSEP included exercises targeting the transversus abdominus and multifidus musculature. The TEP comprised exercises targeting the rectus abdominus, oblique abdominal, and hip flexor musculature.

Measurements. Research staff recorded all injuries resulting in the inability to complete full duty responsibilities. Differences in the percentages of musculoskeletal injuries were examined with chi-square analysis; independent sample *t* tests were used to examine differences in the numbers of days of work restriction.

Results. Of the 1,141 soldiers for whom complete injury data were available for analysis, 511 (44.8%) experienced, during training, musculoskeletal injuries that AQ: 3 resulted in work restrictions. There were no differences in the percentages of soldiers with musculoskeletal injuries. There also were no differences in the numbers of days of work restriction for musculoskeletal injuries overall or specific to the upper extremity. However, soldiers who completed the TEP and experienced a low back injury had more days of work restriction: 8.3 days (SD=14.5) for the TEP group and AQ: 4 4.2 days (SD=8.0) for the CSEP group.

Limitations. A limitation of this study was the inconsistent reporting of injuries during training. However, the rates of reporting were similar between the groups.

Conclusions. The incidences of musculoskeletal injuries were similar between the groups. There was marginal evidence that the CSEP resulted in fewer days of work restriction for low back injuries.

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Traditional Sit-up Training Versus Core Stabilization Exercises in Musculoskeletal Injuries

[Childs JD, Teyhen DS, Casey PR, et al. Effects of traditional sit-up training versus core stabilization exercises on short-term musculoskeletal injuries in US Army soldiers: a cluster randomized trial. *Phys Ther.* 2010;90: xxx–xxx.]

The US Army has incorporated traditional bent-knee sit-ups (with the hands interlocked behind the head) during physical fitness training for many years.[1] Sit-ups test muscular endurance for the abdominal and hip flexor muscles and have validated normative standards based on sex and age.[1] This exercise has been adopted as part of the military's physical training doctrine because of its ease of testing groups of people and the notion that poorer performance of sit-ups on the Army Physical Fitness Test (APFT) has been associated with a higher incidence of musculoskeletal injuries.[2] Sit-ups also are commonly incorporated in general public training routines for the purpose of improving abdominal and hip flexor muscular endurance.

Despite longstanding tradition and the widespread popularity of sit-ups, it has been postulated that this exercise results in increased lumbar spine loading, potentially increasing the risks of injury and low back pain (LBP). Specifically, sit-ups produce large shear and compressive forces on intervertebral disks and across the lumbar spine.[3–5] Increased muscle activation anteriorly results in both initial hyperextension and subsequent hyperflexion of the lumbar spine, contributing to large compressive forces during sit-ups.[6,7]

To address these potential concerns, health and fitness professionals commonly recommend alternative "core stabilization" exercises (also commonly known as "lumbar stabilization" or "motor control" exercises), which comprise abdominal and trunk muscle strengthening exercises, in lieu of sit-ups to improve abdominal muscular fitness.[8] These recommendations are based on the accumulated evidence demonstrating that these exercises selectively activate the key abdominal and trunk musculature (ie, the transversus abdominus, multifidus, erector spinae, and quadratus lumborum muscles) involved in controlling forces across the lumbar spine.[9–13] This literature has demonstrated that these exercises should be prescribed because they are based on controlled-activation, low-load principles, which require minimal trunk movements that better match the function of the muscles and contribute to improved trunk neuromuscular control.[4,7] Advocates of these approaches also cite research indicating that abdominal crunch and trunk stabilization exercises optimize the challenge to the abdominal muscles while minimizing potentially deleterious lumbar spine forces.[3,14] AQ: 5

Core stabilization exercises have been supported by the US Army and advocated for inclusion in US Army physical fitness training programs[15]; however, US Army personnel are still required to take an APFT that incorporates a 2-minute maximal sit-up test. Failure to pass the APFT can have negative consequences on a soldier's career and decrease the chance for promotion; this may be one reason why a core stabilization exercise program (CSEP) has not been widely adopted in the US Army. However, Childs et al[16] recently found that a CSEP did not have a detrimental effect on sit-up performance or overall fitness scores or pass rates. There was a small but significantly greater increase in sit-up pass rates in a group receiving a CSEP (5.6%) than in a group receiving a traditional exercise program (TEP) (3.9%).[16]

Despite recent evidence that incorporating a CSEP into US Army physical training does not increase the risk of suboptimal performance on the APFT,[16] it is important to establish that any newly proposed training programs do not pose unintended consequences, such as an increased risk of musculoskeletal injuries dur- AQ: 6

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ing training. As an example, there have been anecdotal concerns that the horizontal side support exercise (Fig. 1) might contribute to an increase in upper-extremity (UE) injuries because of the prolonged weight bearing through the shoulders that is associated with this exercise. Despite the hypothesized concerns, there are no empirical data indicating whether this exercise actually poses a real injury risk. From a broader health policy perspective, previous studies of soldiers in US Army basic training showed that the incidences of injuries during training varied from 23% to 28% for men and 42% to 67% for women.[17–21] Musculoskeletal injuries during training delay the successful completion of training or result in soldiers having to drop out of training; the end result is substantial lost productivity associated with costs estimated to be in the millions of dollars per year.[2,22–24] An adequate understanding of the potential injury risks associated with any newly proposed training programs is essential to inform policy decision making.

F1 AQ: 7

Figure 1.
Horizontal side support exercise, part of the core stabilization exercise program.

Therefore, the purpose of this study was to explore the short-term effects of a CSEP and a TEP on musculoskeletal injury incidence and work restriction. We hypothesized that there would be no differences between the groups in short-term injury incidence or work restriction. Advancing the understanding of the implications of newly proposed training regimens for short- and long-term injury rates will aid in policy decision making related to the design and implementation of optimal physical training guidelines in the military.

Method

Design Overview

Consecutive soldiers entering a 16-week training program at Fort Sam Houston, San Antonio, Texas, to become combat medics in the US Army were considered for study participation. This study is a report of a planned analysis of the proximal outcome of a clinical trial concerning the prevention of LBP in the military (NCT00373009),[25] which has been registered at http://clinicaltrials.gov.

In the primary trial, soldiers were randomized in clusters to receive a CSEP alone, a CSEP with a psychosocial education program, a TEP, or a TEP with a psychosocial education program. Soldiers are currently being monitored monthly for 2 years after the completion of training to assess the long-term outcomes regarding LBP occurrence and severity. However, the results of the primary trial are not yet available. Because the educational program was not designed to affect injury rates, we collapsed the study population into 2 groups (TEP group and CSEP group) for the purpose of this analysis.

Setting and Participants

Research staff at Fort Sam Houston introduced the study to individual companies of soldiers and obtained written informed consent. Soldiers were recruited during a training orientation session attended by all soldiers as part of their preparation for medic training. For 8 consecutive months, soldiers were screened for eligibility according to the inclusion and exclusion criteria. Soldiers were required to be 18 to 35 years of age (or 17-year-old emancipated minors), participating in training to become combat medics, and able to speak and read English. Soldiers with a prior history of LBP were excluded. A prior history of LBP was operationally defined as LBP that limited work or physical activity, lasted longer than 48 hours, and caused the soldier to seek health care. Soldiers also were excluded if they were currently seeking medical care for LBP; were unable to participate in unit exercise because of an injury in the foot, ankle, knee, hip, neck, shoulder, elbow, wrist, or hand; had a history of fracture (stress or traumatic) in the proximal femur, hip, or pelvis; were pregnant; or had been transferred from another training group. Other possible reasons for exclusion included acceleration into a company that had already been randomized and recruited for participation in the clinical trial concerning the prevention of LBP in the military or reassignment to an occupational specialty other than combat medic.

Figure 2 shows a flow diagram describing the numbers of companies F2

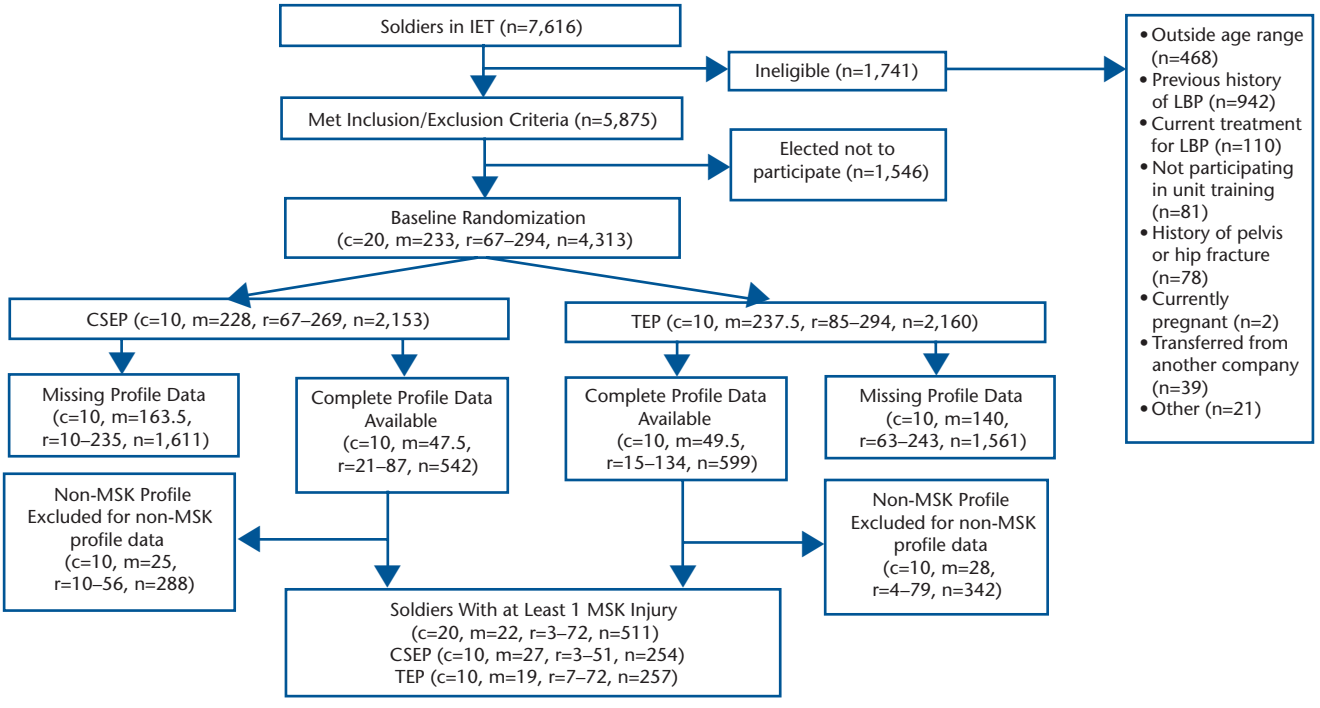

Figure 2.
Flow diagram for participant recruitment and randomization. c=number of companies, CSEP=core stabilization exercise program, IET=initial entry training, LBP=low back pain, m=median company size (number of soldiers), MSK=musculoskeletal, n=total number of soldiers, r=range of company size (number of soldiers), TEP=traditional exercise program.

and soldiers who were considered for the clinical trial, who were eventually enrolled in the trial, and who completed the follow-up assessment, in accordance with the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) statement.[26,27] All soldiers provided written informed consent before participation in the study.

Randomization and Interventions

Military training environments require living in close quarters with other members of the unit, making individual randomization not feasible for this trial because of concerns related to the disruption of the normal training schedule and treatment contamination. Therefore, a cluster randomization strategy was used for assigning companies to receive a TEP or a CSEP. This meant that for a given company, every soldier who consented to the study received the same study condition. Cluster randomization is a viable methodological choice that has been effectively used in other large samples of primary prevention.[28–30] The randomization schedule was prepared by computer before recruitment began and was balanced to ensure equal allocation to both conditions after 20 companies were recruited.

Soldiers in both groups performed the assigned exercise programs in a group setting under the direct supervision of their drill instructors as part of daily unit physical training. The exercise regimens for both groups consisted of 5 or 6 exercises, each of which was performed for 1 minute. Exercise programs were performed daily, for a total dosage time of approximately 5 minutes per day, 4 days per week, over a period of 12 weeks. Performing the exercise programs under the supervision of drill instructors and in a group setting helped to ensure compliance with the assigned program and dosage. Other aspects of standard physical training (ie, warm-up, aerobic training, strength and conditioning drills, and cool-down) were performed to US Army standards by both groups. Additional details regarding each exercise program are given elsewhere.[16]

The soldiers' drill instructors were given comprehensive training in the study procedures by the research staff before the initiation of the study. The drill instructors were given detailed training cards specific to each program. This information also was provided to the drill instructors on the Web site for the study (http://polm.ufl.edu) for reference purposes. This training ensured that both the drill instructors and the soldiers were proficient in their assigned exercise programs and enhanced their ability to accomplish

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the exercise programs in a standardized manner. Study personnel monitored physical training for an average of 2 days per week over the 12-week training period to answer questions and monitor compliance with the assigned exercise programs.

Outcomes and Follow-up

Study-related measures were collected by study personnel who were unaware of the randomization assignments before training and 12 weeks later, when training was completed. All measures were scored in a masked manner by computer algorithm. Soldiers provided standard demographic information, such as age, sex, and past medical history, and completed a variety of health outcome measures. It was not possible to prevent soldiers from being aware of their group assignments because they actively participated in their randomly assigned training programs. However, APFT scores were collected by drill instructors according to the standard testing procedures outlined below.[1] The drill instructors were not formally involved with the study other than within the context of the usual training environment.

As part of the primary trial, research staff aggregated the data on all injuries (musculoskeletal and nonmusculoskeletal) resulting in work restrictions on the basis of information provided by the administrative clerks within the soldiers' units. A *work restriction* was defined as any restriction that resulted in a soldier's inability to complete full duty responsibilities. The administrative clerks recorded injuries resulting in work restrictions on Department of the Army Form 3349 (Physical Profile) according to the US Army's standard reporting procedures. Physical profiling is a system of classifying people according to functional abilities.[31] A profile identifies a soldier's medical condition and functional activity limitations and makes suggestions for accommodative work environments and necessary work restrictions for a specified period of time. Physical profiles are issued by health care providers upon evaluation of a soldier's physical status immediately after an injury is reported. Profiles were collected on a weekly basis by study personnel.

Injuries were first classified as being musculoskeletal or nonmusculoskeletal in origin. Musculoskeletal injuries were injuries that affected the musculoskeletal system and that might have been associated with exercise and military training. Traumatic injuries (eg, a femur fracture) that could not possibly be related to the training regimen were excluded. An example of a nonmusculoskeletal injury would be a condition such as the common cold. Musculoskeletal injuries were further classified according to key body regions of interest (low back, UE, and lower extremity [LE]). We did not report separately the number of neck-related injuries because there was no hypothesis about the potential of a TEP or a CSEP to adversely affect the cervical spine. Low back injuries were defined as those affecting the lumbopelvic region. Upper-extremity injuries were defined as injuries affecting the shoulder, elbow, wrist, or hand. Lower-extremity injuries were defined as injuries affecting the hip, knee, ankle, or foot. In the event an injury crossed over regions (such as low back and hip pain), the injury was classified according to the location of the primary pain. The incidence of injury was determined by counting the number of profiles for each type of injury during training. The duration of injury was recorded as the number of days of work restriction, as annotated on the physical profile form.

Data Analysis

Descriptive statistics, including measures of central tendency and dispersion for continuous variables, were calculated to summarize the data. The demographic and baseline levels of variables were compared between the groups (ignoring clusters) by use of *t* tests for comparison of means and chi-square tests for comparison of proportions.

The exercise groups (CSEP and TEP) were compared for musculoskeletal injury incidence overall and according to body region (low back, UE, and LE) and for work restriction, defined as the number of days of work restriction. Differences in the percentages of musculoskeletal injuries were examined by use of hierarchical logistic regression; differences in the numbers of injuries and the numbers of days of work restriction were analyzed by use of hierarchical Poisson regression. The GLIMMIX procedure was used for the analyses, including a random company effect to model the correlations within clusters. The alpha level was set to .05 *a priori*. Soldiers with missing data were excluded because the purpose of this study was to determine the impact of a CSEP among soldiers who completed the full training period. All statistical analyses were performed with SAS version 9.1.* AQ: 11 Fn*

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Results

Twenty companies with a total of 7,616 soldiers were screened for inclusion in the study. Of these sol-

* SAS Institute Inc, 100 SAS Campus Dr, Cary, NC 27513-2414.

AQ: 18 **Table 1.**
AQ: 19 Demographic and Other Baseline Variables[a]

Variable	All	CSEP Group	TEP Group	*P*
No. of companies	20	10	10	
No. of soldiers	1,141	542	599	
Age, y, $\bar{X}$ (SD)	22.7 (4.6)	22.5 (4.5)	22.7 (4.7)	.745
Sex (% men)	60.9	60.1	61.6	.615
Body mass index, kg/m^2, $\bar{X}$ (SD)	24.9 (3.6)	24.8 (3.2)	24.9 (3.9)	.538
Receiving PSEP (%)	51.6	50.0	53.1	.297
Complete profile data available (%)	26.4	25.2	27.7	.059
Currently smoke (%)	41.2	42.1	41.6	.776
Previous routine exercise (%)	42.7	47.2	44.9	.127
Education, some college (%)	56.3	56.6	55.9	.808
Previous profile (%)	32.4	33.0	32.7	.818

[a] CSEP=core stabilization exercise program, TEP=traditional exercise program, PSEP=psychosocial education program that was part of the larger clinical trial.

diers, 5,875 were eligible to participate. Reasons for ineligibility included being outside the age range (n=468); having a history of LBP (n=942); currently seeking care for LBP (n=110); not participating in unit physical training (n=81); having a history of pelvis or hip fracture (n=78); currently being pregnant (n=2); transfer from another company (n=39); and other, unspecified reasons (n=21). Of the eligible soldiers, 4,329 (73.7%) consented to participate. Complete profile data were available for 1,141 (26.4%) of the randomized soldiers because of inconsistent reporting of profiles (Fig. 2); however, the rates of reporting were similar between the groups (Tab. 1).

The mean age of the soldiers was 22.7 years (SD=4.6 years), and 60.9% were men (Tab. 1). The demographic variables were similar between the exercise groups (Tab. 1). Of the 1,141 soldiers for whom complete profile data were available, 511 (44.8%) experienced at least 1 musculoskeletal injury (254 in the CSEP group and 257 in the TEP group). There were no statistically significant differences in the percentages of soldiers with musculoskeletal injuries overall (42.9% in the TEP group and 46.9% in the CSEP group; *P*=.757) or according to body region: 11.0% in the TEP group and 13.3% in the CSEP group (*P*=.283) for LB, 30.7% in the TEP group and 31.5% in the CSEP group (*P*=.852) for LE, and 4.5% in the TEP group and 6.1% in the CSEP group (*P*=.513) for UE (Tab. 2). Among soldiers with at least 1 musculoskeletal injury (n=511), there were no differences in the incidences of musculoskeletal injuries overall or according to body region (*P*>.05); the average soldier experienced 1.2 injuries during training, and the majority of these injuries were LE injuries (0.8 LE injury per soldier during training) (Tab. 3). Additionally, there were no statistically significant differences in the numbers of days of work restriction for musculoskeletal injuries overall or specific to the LE or UE; means (SD) for musculoskeletal injuries overall were 21.4 (24.7) days in the TEP group and 20.4 (16.9) days in the CSEP group (*P*=.919), those for musculoskeletal injuries specific to the LE were 20.0 (23.8) days in the TEP group and 19.5 (15.6) days in the CSEP group (*P*=.791), and those for musculoskeletal injuries specific to the UE were 19.5 (17.0) days in the TEP group and 24.0 (23.1) days in the CSEP group (*P*=.634). Soldiers who were in the TEP group and who experienced a low back injury did experience more days of work restriction; means (SD) were 8.3 (14.5)

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Table 2.
Musculoskeletal Injuries That Resulted in Work Restrictions Among Soldiers (n=1,141)

Type of Injury	CSEP Group[a]			TEP Group[b]			*P*
	No. of Soldiers	% of Soldiers	Range of Cluster Percentages	No. of Soldiers	% of Soldiers	Range of Cluster Percentages	
Musculoskeletal (any)	254	46.9	14.3–63.8	257	42.9	16.7–73.3	.757
Low back	72	13.3	0–22.7	66	11.0	5.6–19.2	.283
Lower extremity	171	31.5	8.8–50	184	30.7	7.4–53.3	.851
Upper extremity	33	6.1	0–19.6	27	4.5	0–10.0	.513

[a] CSEP=core stabilization exercise program. The CSEP group comprised 10 companies and 542 soldiers.
[b] TEP=traditional exercise program. The TEP group comprised 10 companies and 599 soldiers.

Table 3.
Number of Injuries That Resulted in Work Restrictions in Soldiers With at Least 1 Musculoskeletal Injury (n=511)

Type of Injury	CSEP Group[a]			TEP Group[b]			*P*
	No. of Injuries		Range of Cluster Averages	No. of Injuries		Range of Cluster Averages	
	$\bar{X}$	SD		$\bar{X}$	SD		
Musculoskeletal (any)	1.3	0.5	1.0–1.6	1.2	0.5	1.0–1.4	.699
Low back	0.3	0.6	0–0.5	0.3	0.5	0.2–0.5	.616
Lower extremity	0.8	0.6	0.5–1.1	0.8	0.6	0.4–1.0	.809
Upper extremity	0.1	0.3	0–0.3	0.1	0.3	0–0.2	.888

[a] CSEP=core stabilization exercise program. The CSEP group comprised 10 companies and 254 soldiers.
[b] TEP=traditional exercise program. The TEP group comprised 10 companies and 257 soldiers.

days in the TEB group and 4.2 (8.0) days in the CSEP group (P=.083) (Tab. 4).

Discussion

The results of the present study indicate that a CSEP does not result in increased incidence or duration of musculoskeletal injuries during training. Furthermore, the data refute anecdotal concerns that have been raised regarding the horizontal side support exercise (Fig. 1) in a CSEP increasing the potential to experience a UE injury. Approximately 5% of all injuries (musculoskeletal and nonmusculoskeletal) during training were UE injuries; however, there were no differences in UE injury rates between the groups (Tab. 2). The most common injuries were LE injuries, which accounted for more than 30% of all injuries, followed by low back injuries (12%) (Tab. 2). These data confirm those of previous studies demonstrating that low back and LE injuries are the most common injuries experienced during training.[2,24]

Soldiers with UE and LE injuries experienced similar numbers of days of work restriction regardless of exercise group (20–24 days) (P>.05) (Tab. 4); however, soldiers who experienced a low back injury did experience more days of work restriction with the TEP than with the CSEP: 8.3 (14.5) days and 4.2 (8.0) days, respectively (P=.083) (Tab. 4). Although this finding is not statistically significant, a potentially relevant effect may be emerging, as demonstrated by a between-group effect size of .37. Given the evidence from the biomechanical literature demonstrating that sit-ups produce large shear and compressive forces on intervertebral disks and across the lumbar spine,[3–5] perhaps the trend toward a short-term increase in the number of days of work restriction in association with the TEP is attributable to these suboptimal biomechanical effects. Another possibility is that the increase in the number of days of work restriction indicates an early protective benefit of the CSEP with respect to low back injuries. However, in light of the marginal P value, combined with the fact that we would not expect to detect a difference in work restriction in response to the CSEP over such a short period of time, this interpretation should be viewed with caution. Whether the CSEP is protective against the development of low back injuries will be established more definitively once the 2-year follow-up is complete.

One of the potential limitations of the present study was the inconsistent reporting of injuries during

Table 4.
Number of Limited-Duty Days That Resulted in Work Restrictions in Soldiers With at Least 1 Musculoskeletal Injury

Type of Injury	CSEP Group[a]			TEP Group[b]			*P*
	No. of Days		Range of Cluster Averages	No. of Days		Range of Cluster Averages	
	$\bar{X}$	SD		$\bar{X}$	SD		
Musculoskeletal (any)	20.4	16.9	14.1–28.8	21.4	24.7	10.6–28.5	.919
Low back	4.2	8.0	0–5.8	8.3	14.5	0–18.2	.083
Lower extremity	19.5	15.6	15.4–28.0	20.0	23.8	8.8–26.6	.791
Upper extremity	24.0	23.1	7.0–33.2	19.5	17.0	0–44.5	.634

[a] CSEP=core stabilization exercise program. The CSEP group comprised 10 companies and 254 soldiers.
[b] TEP=traditional exercise program. The TEP group comprised 10 companies and 257 soldiers.

training; therefore, the absolute number of injuries reported during training likely was underestimated. However, the rates of reporting were equally represented across the groups (Tab. 1). Another potential limitation is that although we excluded soldiers with a current or a previous history of LBP or other injuries that would interfere with the successful completion of unit physical training, we did not control for previous non–low back musculoskeletal injuries, except those that would interfere with the completion of unit physical training. However, because we excluded soldiers with any previous low back injuries and soldiers with non–low back musculoskeletal injuries that would interfere with the successful completion of unit physical training, it is unlikely that a previous history of nonserious musculoskeletal injuries would have contributed to current injury complaints during training.

Despite evidence from the biomechanical literature supporting the potential benefits of a CSEP as well as current literature illustrating that a CSEP does not result in decreased performance on the APFT,[16] more definitive research on the potential long-term protective effects of a CSEP on injury rates is needed. We propose that future research consider the potential of a CSEP to prevent musculoskeletal injuries, such as LE and low back injuries, in the long term. We also propose conducting a similar study outside military training environments to determine whether the results can translate to the general population.

These early data provide confidence that a long-term study of a CSEP in military training environments can be successfully carried out without increasing the risks of musculoskeletal injuries or decrements in fitness test scores, as previously reported.[16] These data, in addition to the long-term results of the primary trial, will assist health care professionals and policy makers in designing optimal military physical training programs that best maintain optimal physical fitness, maximize performance, and minimize potential injuries in both the short term and the long term. There also may be applications for clinicians, who could recommend these exercises as part of wellness or fitness routines.

Conclusions

The results of the present study demonstrated that the CSEP did not increase the incidence of musculoskeletal injuries or days of work restriction during training, regardless of the involved body region. In fact, the TEP resulted in approximately 4 more days of work restriction than the CSEP. These results may be explained by the increased shear and compressive forces across the lumbar spine during sit-ups[3–5] or may attest to an early protective effect of the CSEP. Future research should aim to determine whether the CSEP has long-term protective effects on common musculoskeletal injuries, such as LE and low back injuries.

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